ACEPHEN - acetaminophen suppository Cosette Pharmaceuticals, Inc.

Pediatric AcephenTM Acetaminophen Suppositories USP, 120 mg

ACTIVE INGREDIENT (in each rectal suppository)

Acetaminophen 120 mg

PURPOSE

Pain reliever/fever reducer

USES

temporarily

- reduces fever
- relieves minor aches, pains, and headache

WARNINGS

For rectal use only

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if your child inserts

- more than 5 suppositories in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- if your child is allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if your child has liver disease

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- fever lasts more than 3 days (72 hours), or recurs
- you need to use this product for pain for more than 5 days continuously

Severe or recurrent pain, or high or continued fever may indicate a serious illness.

Keep out of reach of children.

If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for children even if you do not notice any signs

or symptoms.

Directions

This product does not contain directions or complete warnings for adult use.

- · do not use more than directed
- remove foil wrapper
- insert suppository well up into rectum
- children 3-6 years
 - 1 suppository every 4 to 6 hours while symptoms persist
 - do not exceed 5 suppositories in any 24-hour period
- children under 3 years: ask a doctor

Other Information

- for your safety, suppositories are packaged in tamper-evident sealed foil. Do not use if foil is torn or open.
- store at 8°-25°C (46°-77°F)

Inactive ingredients

butylated hydroxyanisole, butylated hydroxytoluene, glyceryl stearate, hydrogenated vegetable oil, polyethylene glycol 100 stearate, polysorbate 80

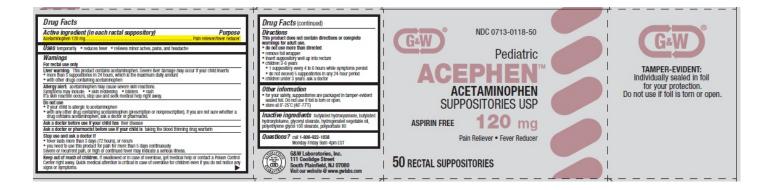
Questions?

call **1-800-922-1038** Monday-Friday 9am-4pm EST

PRINCIPAL DISPLAY PANEL

NDC 0713-0118-50 G&W Pediatric ACEPHENTM Acetaminophen Suppositories USP 120 mg ASPIRIN FREE Pain Reliever • Fever Reducer 50 Rectal Suppositories

08/2013



ACEPHEN

acetaminophen suppository

Product	Information
Product	IIIIVI IIId UVII

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0713-0118
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Route of Administration RECTAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength			
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	120 mg			

Inactive Ingredients

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Ingredient Name	Strength	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
HYDROGENATED COCONUT OIL (UNII: JY810XM10M)		
PEG-8 STEARATE (UNII: 2P9L47VI5E)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		

Packaging

ı	Раскадия			
#	Item Code	Item Code Package Description		Marketing End Date
1	NDC:0713-0118-12	12 in 1 BOX; Type 0: Not a Combination Product	0 1/0 1/19 8 2	
2	NDC:0713-0118-01	100 in 1 BOX; Type 0: Not a Combination Product	0 1/0 1/19 8 2	
3	NDC:0713-0118-50	50 in 1 BOX; Type 0: Not a Combination Product	0 1/0 1/19 8 2	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018060	0 1/0 1/19 8 2	

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals, Inc.		116918230	analysis(0713-0118), manufacture(0713-0118), label(0713-0118), pack(0713-0118)

Revised: 7/2019 Cosette Pharmaceuticals, Inc.